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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,203	04/25/2000	SUZANNE DE LA MONTE	0609.4370001	2325

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STERNE KESSLER GOLDSTEIN & FOX
1100 NEW YORK AVENUE NW
SUITE 600
WASHINGTON, DC 200053934

EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/380,203	DE LA MONTE ET AL.
	Examiner	Art Unit
	Brian Whiteman	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,10-13,35-37,39-47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,10-13,35-37,39-47 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 1-3, 5, 6, 10-13, 35-37, 39-47, and 49 are pending.

In view of the Board of Appeals' decision the finality of that action is withdrawn.

The indicated allowability of claims 39-43 and 49 is withdrawn in view of the newly discovered reference(s) to WO 94/23756. Rejections based on the newly cited reference(s) follow.

Specification

The disclosure remains objected to because of the following informalities: the status (e.g., pending, abandoned, patented US Patent No.) of US applications listed on pages 14 and 20-21 is missing.

In paper filed on 7/7/03, applicants request that this ground of objection be held in abeyance until the remaining issues in this application are resolved.

The objection to the disclosure remains for the reasons set forth above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 and 44-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method for screening a drug that is potentially

useful for the treatment or prevention of Alzheimer's disease, does not reasonably provide enablement for using the claimed method for screening drugs that could be potentially useful for treating neuroectodermal tumors, malignant astrocytomas or glioblastomas. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claimed invention encompasses an in vitro method for screening drugs that could be potentially useful for the treatment of prevention of Alzheimer's disease, neuroectodermal tumors, malignant astrocytomas, or glioblastomas.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)).

First, the specification is not enabling for the full breadth of the claimed invention because the specification does not teach how to use the in vitro method for screening drugs that are potentially useful for treating or preventing neuroectodermal tumors, astrocytomas, or glioblastomas. The specification on page 6 makes a general statement, which reiterates what is

recited in the instantly presented claims. The specification teaches that over-expression of Ad7c-NTP results in apoptosis in neuronal cells in vitro (page 46) and is associated with neurodegeneration in post-mortem human brains (page 18). The specification and the prior art are absent about the activity of Ad7c-NTP with regard to brain tumors. Other than the statement in the specification that the claimed method can be used to screen drugs for the recited tumors, the specification fails to disclose how detecting any of the characteristics (i)-(iii) can be used to screen for drugs potentially useful for the treatment or prevention of brain tumors. The pathology of AD and brain tumors is different. For example, AD is the result of cell death and brain tumors are the result of uncontrolled growth of cells. Also, the skilled artisan understands that goal of cancer is to kill cancer cells and the characteristics recited in the methods would prevent the killing of the cells. In summary, neither the art of record nor the specification as filed teaches how to use the claimed methods for screening a drug that could be potentially useful for the treatment or prevention of neuroectodermal tumors, astrocytomas, or glioblastomas.

In conclusion, the specification does not provide sufficient guidance for an artisan of skill to have practiced the claimed invention commensurate with the full scope of the claims and therefore, limiting the scope of the claimed invention to an in vitro method for screening a drug that is potentially useful for the treatment or prevention of Alzheimer's disease is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 35-37, 39-43 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/23756 (cited on an IDS). De La Monte teaches a DNA sequence labeled as AD10-7, which on page 5 of the instant specification applicant state that AD7c-NTP cDNA from an AD brain expression library was cloned and referred to AD10-7 and deposited at ATCC under accession no. 69262 and its sequence was published in Figure 16R of WO 94/23756. Applicant further state that the sequence in Figure 16R was published with numerous errors and are labeled SEQ ID NO: 3 and 4 in the instant specification. In view of applicant's assertion on page 5 of the instant specification, the sequence in SEQ ID NO: 1 is the same DNA as the DNA in SEQ ID NO: 3 and 4 but with corrections. See Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) and Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51USPQ2d 1307, 1310 (Fed.Cir.1999). De La Monte teaches linking the cDNA to a heterologous promoter (pages 22-25 and 77). De La Monte teaches the limitation in instant claims 2, 3, 40, and 41 (pages 55-56 and 77). De La Monte teaches the limitation instant claims 5, 6, 42, and 43 (pages 20 and 95-96).

Response to Arguments

In view of the Decision by the Board on 8/30/05, applicant's arguments with respect to 112 first paragraph written description have been fully considered and are persuasive. The rejection of claims 1-3, 5, 6, 10, 12, and 13 has been withdrawn.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

Bruce M. Kisliuk, Director
Technology Center 1600

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